UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,825	01/23/2004	Jan Weber	1001.2246101	5021

11050 7590 02/16/2011

SEAGER, TUFTE & WICKHEM, LLC
1221 Nicollet Avenue
Suite 800
Minneapolis, MN 55403

EXAMINER	
MCEVOY, THOMAS M	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
02/16/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,825	WEBER ET AL.	
	Examiner	Art Unit	
	THOMAS MCEVOY	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,30-32,36,37,43,50,53-59,62,63,65,66,78,79 and 85-95* is/are pending in the application.

4a) Of the above claim(s) *43,53,55,58,59,62,65,66,78 and 79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,30-32,36,37,50,54,56,57,63 and 85-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 28, 30-32, 36, 37, 50, 54, 56, 57, 63 and 85-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 6,514,237) in view of Couvillon (US 2003/0236531).

Regarding claim 28, a medical device comprising an elongate body 114 adapted for insertion into a body lumen, said elongate body having distal and proximal ends and an axis; an inflatable balloon 118 disposed about a distal region (magnified section, Figure 5) of the elongate body; and an active region comprising a conductive polymer 500 disposed over the elongate body. Maseda fails to disclose that the conductive polymer is at least partially beneath the balloon. Maseda discloses: the electroactive polymer strands may be incorporated into various segments (or any segment) of the device so that the device expands like and mimics a balloon in a balloon catheter (col. 3, lines 3- 6); the circumferentially arranged band of composite strands expands and functions like a balloon (col. 6, lines 47-59); the balloon itself may incorporate the composite strands (col. 8, lines 6-9). Therefore, it would have been obvious to one of ordinary skill in the art to have incorporated the conductive polymer strips 500 in the balloon, on the balloon or under the balloon in order to expand the balloon, as it would

be readily apparent to one of ordinary skill in the art that the balloon could be expanded by the strips with either orientation. Maseda fails to specifically disclose other types of electroactive polymers, such as those which are actuated by volumetric expansion, but clearly indicates that the electroactive polymer used in his disclosure is for explanatory purposes only (col. 4, lines 44-48). Couvillon discloses the device as previously made of record which utilizes circumferentially arranged, longitudinal strips 110 (Figure 4 or 7A/B embodiments) which comprise a volumetrically expanding electroactive polymer 112. It would have been obvious to one of ordinary skill in the art to have used the strips of Couvillon to expand the balloon of Maseda because alternate forms of electroactive polymers are suggested by Maseda and the Couvillon arrangement of strips closely resembles that 500 of Maseda. Couvillon also discloses that the strips can be arranged under a radially expanding member 104 in order to expand it to a cross-sectional shape resembling the cross-sectional shape of a balloon. This would provide further motivation to place the strips under the balloon of Maseda. With this combination the strips would contain a passive deformable member 120 disposed over the elongate body and beneath the inflatable balloon, wherein, when the active region is exposed to an electrical potential, the active region would cause the passive deformable member to expand in at least one radial dimension moving at least a portion of the inflatable balloon from a substantially uninflated state to a first expanded state. Regarding claim 30, the passive deformable member is adapted to radially advance a proximal portion of the inflatable balloon when the active region is exposed to the electrical potential (evident from the above explanation – all portions of the balloon are

intended to radially advance). Regarding claim 31, the passive deformable member is adapted to radially advance proximal and distal portions of said inflatable balloon when said active region is exposed to said electrical potential (evident from the above explanation). Regarding claim 32, passive deformable member is adapted to radially advance proximal, central and distal portions of said inflatable balloon when said active region is exposed to said electrical potential (evident from the above explanation). Regarding claim 36, since the ends of the strips meet in a continuous circumferential band and are attached to the actuators 110 in Couvillon (Figure 8A and 8B), it would have been obvious to one of ordinary skill in the art to have provided the actuators in this form since there geometry disclosed and they could function as a band or as strips. Regarding claim 37, active region is provided over said elongate body in the form of a longitudinal member (see Figures 4 or 7A/7B of Couvillon). Regarding claim 50, 54, 56, 57 and 85, Maseda discloses a balloon catheter as described above and capable of expanding a stent, comprising: a catheter shaft 116 adapted for insertion into a body lumen of a patient, said catheter shaft defining an inflation lumen (defines interior circumference of lumen – Figure 2); an inflatable balloon 118 disposed about a distal region of said catheter shaft, wherein the interior of said inflatable balloon is in fluid communication with said inflation lumen (col. 4, lines 20-24). Maseda fails to disclose the above strips in a recess as claimed. Maseda does disclose that the active region or strips can be disposed in grooves in catheter 114 (col. 6, line 44 – referring to mechanical means disclosed in col. 5, lines 60-61). Therefore, with the above modification, it would have been obvious to one of ordinary skill in the art to have

disposed the strips in grooves or recesses in catheter 116. With the above combination it is evident that an inner surface of the one or more electrically actuated members is attached to an outer surface of the catheter shaft 116 and an outer surface of the one or more electrically actuated members is configured to be in contact with an inner surface of the inflatable balloon, wherein, when activated, said one or more electrically actuated members radially expand such that the outer surface of the one or more electrically actuated members contacts the inner surface of the inflatable balloon and transforms said inflatable balloon from a radially contracted state in which said balloon catheter is more readily inserted into said body lumen of said patient to a first radially expanded state, wherein said inflatable balloon is configured to be further expanded to a second radially expanded state with an inflation media received via the inflation lumen, wherein the second radially expanded state is larger than the first radially expanded state. Maseda fails to explicitly disclose a stent. Maseda discloses that the invention addresses the problem of steering stent-carrying angioplasty balloons (col. 1, lines 14-32). Therefore, it would have been obvious to one of ordinary skill in the art to have used the Maseda device to deliver a stent placed on the balloon in order to provide better steering. Regarding claim 86, a sealed structure 120 (of Couvillon) encloses the active region, an electrolyte 114 and a counter electrode 118. Regarding claims 87-89, as claimed members 118 of Couvillon can be considered as the radiopaque bands (paragraph 0074) and member 114 (Figure 10C) or 120 (Figure 10A) can be considered as the active region. Regarding claim 90, the proximal marker and the distal marker are configured to have an outer diameter that is greater than the outer

diameter of the one or more electrically actuated members when the one or more electrically actuated members are in a non-activated state (Figure 10A). Regarding claim 91, a first marker (proximal 112; Figure 10B) is slidably disposed about the elongate body and engaged to the active region; and a second marker (distal 112; Figure 10B) fixedly disposed about the elongate body, and wherein the passive deformable member is disposed between the proximal marker and the distal marker (Figure 7A and 7B). Regarding claim 92, the active region causes the passive deformable member to expand in at least one radial dimension by sliding the first marker along the elongate body towards the second marker (Figures 7A and 7B). Regarding claim 93, the first marker is proximal of the second marker (several members 112 would be proximally located in the Figure 7A and 7B embodiment and would slide as claimed). Regarding claims 94 and 95, Maseda fails to disclose that the balloon is rubber or elastic, however, this material is well-know in the art for dilation balloons similar to 118 and it would have been obvious to one of ordinary skill in the art to have constructed the balloon of Maseda from these materials.

Response to Arguments

Applicant's arguments filed November 23rd 2010 have been fully considered but are moot in view of the new combination between Maseda and Couvillon.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571)270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas McEvoy/
Examiner, Art Unit 3731